

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-0160002	Application No. 09/993,669
		Applicant Ann-Kristin Karlsson et al.	
		Filing Date November 27, 2001	Group Art Unit 1623

**Information Disclosure Statement
by Applicant**
(Use several sheets if necessary)

(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	1	Product description for Rhinocort Aqua® (budesonide), Nasal Spray 32 mcg, 2 pages, dated 01/05
	2	Pulmicort Turbuhaler® (budesonide inhalation powder), 4 pages, dated 10/06
	3	Astra Draco Specification for micronized budesonide prepared for use in the Rhinocort Aqua® nasal spray product, 2 pages, dated 11/20/95
	4	Astra Draco Specification for budesonide prepared for use in the Pulmicort Turbuhaler® product, 2 pages, dated 04/01/97
	5	US Pharmacopeia 23/NF18, pages 1686-1690 and 1963-1975, published by United States Pharmacopeial Convention, Inc., Rockville, MD (1995)
	6	Specification for Pulmicort Respules®, 3 pages, GEL Version ID: RITA.000-243-420.3.0, printed on 06/15/08
	7	US Pharmacopeia 23, "Microbial Limit Tests" USP <61>, pages 1681-1686, published by United States Pharmacopeial Convention, Inc., Rockville, MD (1995)
	8	Astra Draco Specification for PULMICORT 200 TURBUHALER®, 5 pages, dated 09/17/97
	9	Astra Draco Specification for RHINOCORT® nasal spray, 1 page, dated 04/22/91
	10	"Guidance for Industry: Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 4 pages, November 2001
	11	Pulmicort Respules® (budesonide inhalation suspension) product information, 6 pages, dated 6/07
	12	Astra Draco Specification for Pulmicort® suspension for Nebulizing product, 2 pages, dated 02/23/1994
	13	Recorded minutes of a 11/20/96 pre-NDA meeting attended by Astra USA, Astra Draco, and FDA officials, 6 pages
	14	Astra Draco Specification for "budesonide micronized sterile", 2 pages, dated 11/18/1983
	15	Astra Draco documentation (in Swedish) of Manufacturing Method for Preferid® cream dated 09/09/1980, 5 pages, and English translation, 5 pages
	16	Internal Astra Draco document "Establishment of limits for content and related foreign steroids in budesonide substance" dated 03/26/1980, 5 pages
	17	Internal Astra Draco document "Limits for content and related foreign steroids in budesonide substance," dated 11/04/1980
	18	Internal Astra Draco document "Analytical Certificate", dated 08/28/1980, in Swedish, 1 page, with English translation, 1 page
	19	Internal Astra Draco document "Analytical Certificate", dated 09/14/1978, in Swedish, 1 page, with English translation, 1 page
	20	Internal Astra Draco document "Analytical Certificate", dated 02/28/1980, in Swedish, 1 page, with English translation, 1 page
	21	Internal Astra Draco document "Analytical Certificate", dated 02/28/1980, in Swedish, 1 page, with English translation, 1 page
Examiner Signature /Leigh Maier/		Date Considered 01/30/2009

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Ann-Kristin Karlsson et al.	
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(37 CFR 51.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)		
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	22	Internal Astra Draco document "Analytical Certificate", dated 03/28/1980, in Swedish, 1 page, with English translation, 1 page
	23	Internal Astra Draco document "Analytical Certificate", dated 03/28/1980, in Swedish, 1 page, with English translation, 1 page
	24	Internal Astra Draco document "Analytical Certificate", dated 06/09/1980, in Swedish, 1 page, with English translation, 1 page
	25	Internal Astra Draco document "Analytical Certificate", dated 05/04/1979, in Swedish, 1 page, with English translation, 1 page
	26	Internal Astra Draco document "Analytical Certificate", dated 05/04/1979, in Swedish, 1 page, with English translation, 1 page
	27	Internal Astra Draco document "Analytical Certificate", dated 05/08/1979, in Swedish, 1 page, with English translation, 1 page
	28	Internal Astra Draco document "Analytical Certificate", dated 12/12/1978, in Swedish, 1 page, with English translation, 1 page

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